AT

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,282	12/20/2001	Paul Young	PZ007G62AP1D1	4789

22195 7590 05/14/2004

HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
ROCKVILLE, MD 20850

EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,282	YOUNG ET AL.	
	Examiner	Art Unit	
	David J Blanchard	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-75 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-75 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/20/01.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-75 are pending and under examination.

Specification

2. The disclosure is objected to because of the following informalities:

a. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

b. It is requested that Applicant update the priority information in the first line of the specification with the patent number for USSN 09/205,258. The patent number is 6,525,174.

c. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should limit the title to the claimed invention.

Appropriate correction is required.

Claim Objections

3. Claims 54 is objected to because of the following informalities:

Claim 54 (part d) recites "amino acid residues the polypeptide", which is missing the word "of" between "residues" and "the".

Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-75 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility.

The claims are drawn to an isolated antibody or fragment thereof that specifically binds to a protein whose sequence consists of amino acid residues 1-136 of SEQ ID NO:310 (full-length polypeptide encoded by the HEMAE80 cDNA contained in ATCC Deposit Number 97975) and an antibody or fragment thereof that binds to a glycosylated protein consisting of amino acid residues 25-136 of SEQ ID NO:310 (mature form polypeptide encoded by the HEMAE80 cDNA contained in ATCC Deposit Number 97975), wherein the antibody is a monoclonal, polyclonal, chimeric, humanized, human or Fab fragment, which is labeled. Further, the claims are drawn to a cell and a hybridoma that produces the monoclonal antibody that binds to the glycosylated protein consisting of amino acid residues 25-136 of SEQ ID NO:310. The utility and enablement of the antibody depends upon whether or not the polypeptide it binds has utility and enablement. The specification teaches that the gene encoding SEQ ID NO:310 is a secreted protein (see page 327). The specification teaches that the gene

encoding SEQ ID NO:310 (i.e., Gene No:62) is primarily expressed in fetal liver and fetal spleen (see page 98, line 25).

The specification teaches that the tissue distribution of the gene encoding SEQ ID NO:310 indicates that the gene *could be important* for the treatment or detection of immune or hematopoietic disorders including arthritis, leukemia, and immunodeficiency diseases (see page 99, lines 5-7). "Moreover, the protein product of this gene is useful for the treatment and diagnosis of hematopoetic related disorders such as anemia, pancytopenia, leukopenia, thrombocytopenia or leukemia since stromal cells are important in the production of hematopoietic lineages." (see page 99, lines 7-11). The gene product *may also be involved* in lymphopoiesis (the formation of lymphocytes), therefore, it can be used in immune disorders such as infection, inflammation, allergy, immunodeficiency, ect (see page 99, lines 13-15). The specification further states "Moreover, expression within fetal tissue indicates that this protein may play a role in the regulation of cellular division, and *may show utility* in the diagnosis and treatment of cancer and other proliferative disorders." (see page 99, lines 17-19). The specification also teaches that the protein of SEQ ID NO:310 *may also be involved* in apoptosis or tissue differentiation and could again be useful in cancer therapy (see page 99, lines 21-22). Thus, based on the expression of the gene encoding the polypeptide of SEQ ID NO:310 and not the expression of the polypeptide of SEQ ID NO:310, the specification generally asserts that SEQ ID NO:310 *may be useful* for a number of purposes; however, none of these asserted uses meet the "specific" and "substantial" utility requirements of 35 U.S.C. § 101. The asserted utilities will each be addressed in turn.

1) the polypeptide of SEQ ID NO:310 can be used for the "diagnosis of diseases and conditions which include, but are not limited to, hematopoietic, immunological, developmental, and/or hepatic disorders": this asserted utility is not specific or substantial. Since the disease or condition is unspecified and there are many such conditions, the asserted utility is not specific to the claimed polypeptide of SEQ ID NO:310. A generic statement of diagnostic utility, such as diagnosing an unspecified disease, is insufficient absent evidence of specific autoimmune disorders that can be diagnosed. Additionally, the generic statement that the polypeptide is useful for the diagnosis of "hematopoietic, immunological, developmental, and/or hepatic disorders", which does not identify any particular disorder does not support a substantial utility. Further research would be required to identify which of the numerous hematopoietic, immunological, developmental, and/or hepatic disorders that SEQ ID NO:310 is expressed in, the level of expression as well as the function or role the protein plays. Furthermore, since the specification does not disclose the tissue or cell-specific expression of the polypeptide of SEQ ID NO:310 and how the polypeptide can be used, significant further research would be required of the skilled artisan to determine the tissue-specific expression of the polypeptide of SEQ ID NO:310 and how to use the claimed polypeptide. Since the asserted utility is not presented in a ready to use, real-world application, the asserted utility is not substantial.

2) the polypeptide of SEQ ID NO:310 and antibodies directed to the polypeptide of SEQ ID NO:310 are useful in providing immunological probes for differential identification of the tissue(s) or cell type(s): this asserted utility is not specific. Since the

same can be done with any polypeptide, the asserted utility is not specific to the claimed polypeptide. All polypeptides have a tissue-specific pattern of expression, and thus, virtually any polypeptide can be used for this purpose. Furthermore, the tissue-specific pattern of expression for SEQ ID NO:310 is not disclosed. The skilled artisan would have to determine the tissue-specific pattern of expression empirically. Thus, the asserted utility is also not substantial.

3) the polypeptide of SEQ ID NO:310 can be used in immunotherapy: this asserted utility is not specific or substantial. Since a defect in any polypeptide is likely to cause a disease of some sort, every polypeptide is a target for drug development. Thus, the asserted utility is not specific to the claimed polypeptide of SEQ ID NO:310. Furthermore, the specification does not disclose a nexus between any specific disease state and a change in the amount or form of the polypeptide of SEQ ID NO:310. Significant further research would have to be conducted to identify such a nexus. Therefore, the asserted utility is not substantial, as the real-world use has not been identified.

4) the polypeptide of SEQ ID NO:310 is involved in the proliferation and differentiation of cells: this is not a specific utility since there are many such conditions and specific target cells have not been identified. Thus, the asserted utility is not specific to the claimed polypeptide of SEQ ID NO:310. Furthermore, since no specific disease state or disorder has been correlated with the expression of SEQ ID NO:310, further research is required to determine a nexus between the expression of SEQ ID

NO:310 and a specific disease state. Thus, the asserted utility is also not substantial, as the real-world use has not been established.

Therefore, the specification does not support a specific and substantial asserted utility or a well-established utility regarding the claimed antibodies because the polypeptide (i.e., SEQ ID NO:310) to which the antibodies bind does not have a specific and substantial asserted utility or a well-established utility. The proposed antibodies of the claimed invention are simply starting points for further research and investigation into potential practical uses of the polypeptide of SEQ ID NO:310. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner v. Manson*, 148 USPQ at 696.

6. Claims 1-75 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 6, 16 and 37-75 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

a. Claims 16, 37, 53 and 75 are indefinite for reciting "hybridoma that produces the antibody or fragment thereof". Does the hybridoma produce an antibody fragment or does the hybridoma produce the antibody from which an antibody fragment can be produced?

b. Claims 38-75 are indefinite for reciting "full-length form of the polypeptide encoded by the HEMAE80 cDNA contained in ATCC Deposit No. 97975" and "mature form of the polypeptide encoded by the HEMAE80 cDNA contained in ATCC Deposit No. 97975" in claims 38, 54 and 61. It is unclear if the HEMAE80 cDNA contained in ATCC Deposit No. 97975 encodes the secreted polypeptide and the full-length polypeptide, since the secreted HEMAE80 polypeptide has 24 fewer amino acids (see page 197 in the specification) than the full-length HEMAE80 polypeptide and that full-length polypeptide would not be encoded by the same cDNA, which encodes the secreted HLHFP03 polypeptide. Are there two cDNA clones deposited as ATCC Deposit No. 97975, one HEMAE80 cDNA clone encoding the full-length form of the polypeptide and another HEMAE80 cDNA clone encoding the mature form of the polypeptide or does the cDNA clone contained in ATCC Deposit No. 97975 encode the full-length HEMAE80 polypeptide, which can be processed into the secreted HLHFP03 polypeptide?

c. Claims 6, 43 and 66 are indefinite for reciting "specifically binds protein (b)." Claims 6, 43 and 66 are dependent upon parent claims (2, 39 and 62, respectively), which recite an "antibody that specifically binds protein (a)." Thus, an antibody that is specific for protein (a) would not also be specific for protein (b), since an antibody

specific for protein (a) inherently binds to an epitope within amino acid residues 1-24 of SEQ ID NO:310.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

a. The claims are drawn to an isolated antibody or fragment thereof that specifically binds to a protein whose sequence consists of amino acid residues 1-136 of SEQ ID NO:310 (full-length polypeptide encoded by the HEMAE80 cDNA contained in

ATCC Deposit Number 97975) and an antibody or fragment thereof that binds to a glycosylated protein consisting of amino acid residues 25-136 of SEQ ID NO:310 (mature form polypeptide encoded by the HEMAE80 cDNA contained in ATCC Deposit Number 97975), wherein the antibody is a monoclonal, polyclonal, chimeric, humanized, human or Fab fragment, which is labeled. Further, the claims are drawn to a cell and a hybridoma that produces the monoclonal antibody that binds to the glycosylated protein consisting of amino acid residues 25-136 of SEQ ID NO:310.

The specification teaches that the gene encoding SEQ ID NO:310 (Gene No. 62) is primarily expressed in fetal liver and fetal spleen (see page 98, line 25) and SEQ ID NO:238 is a secreted protein (see page 327). Based on the tissue distribution of the gene and not the polypeptide, applicant asserts that the polypeptide of SEQ ID NO:310 and antibodies directed to the polypeptides are useful as reagents for the differential identification of the tissue(s) or cell type(s) present in a biological sample and for the diagnosis of diseases and conditions, which include, but are not limited to, hematopoietic, immunological, developmental, and/or hepatic disorders." (see page 98). Further, the specification states "The gene product *may also be involved* in lymphopoiesis, therefore, it can be used in immune disorders such as infection, inflammation, allergy, immunodeficiency, ect." (see page 99, lines 13-15). Based on gene expression and not protein expression in fetal tissue, the specification teaches that the protein *may also be involved* in apoptosis or tissue differentiation and *could be useful* in cancer therapy (see page 99, lines 21-22). "Protein, as well as, antibodies

directed against the protein *may show utility* as a tumor marker and/or immunotherapy targets for the above listed tissues." (see page 99, lines 22-24).

What the specification does not do is teach the expression of the protein of SEQ ID NO:310 in any specific tissue nor does the specification correlate the expression of SEQ ID NO:310 with any particular disease state and the specification does not teach whether SEQ ID NO:310 would be overexpressed or underexpressed in a particular disease state such that an antibody, which specifically binds SEQ ID NO:310 would be useful for immunotherapy.

The specification does not reasonably provide enablement for antibodies that specifically bind SEQ ID NO:310 based on the written disclosure alone. Those of skill in the art recognize that expression of mRNA (i.e., gene expression), specific for a tissue type, does not necessarily correlate nor predict equivalent levels of polypeptide expression. In fact, evidence abounds in which protein levels do not correlate with steady-state mRNA levels or alterations in mRNA levels. For example, Fu et al (EMBO Journal, 1996, Vol. 15, pp. 4392-4401) teach that levels of p53 protein expression do not correlate with levels of p53 mRNA levels in blast cells taken from patients with acute myelogenous leukemia, said patients being without mutations in the p53 gene. Further, Powell et al (Pharmacogenetics, 1998, Vol. 8, pp. 411-421, abstract) teach that mRNA levels for cytochrome P450 E1 did not correlate with the level of corresponding protein, and conclude that the regulation of said protein is highly complex. Vallejo et al (Biochimie, 2000, vol. 82, pp. 1129-1133, abstract) teach that no correlation was found between NRF-2 mRNA and protein levels suggesting post-transcriptional regulation of

NRF-2 protein levels. Lewin B. (Genes VI, 1997, CH. 29, pp. 847-848) states "But having acknowledged that control of gene expression can occur at multiple stages, and that production of RNA cannot inevitably be equated with production of protein, it is clear that the overwhelming majority of regulatory events occur at the initiation of transcription" (see page 847, right column). These references serve to demonstrate that the analysis of levels of polynucleotide transcripts cannot be relied upon to anticipate levels of protein expression. Further, Jang et al (Clinical and Experimental Metastasis, 1997, vol. 15, pp. 469-483, abstract) teach that further studies are necessary to determine if changes in protein levels track with changes in mRNA levels for metastasis associated genes in murine tumor cells, thus providing further evidence that one of skill in the art cannot anticipate that the level of a specific mRNA expressed by a cell will be paralleled at the protein level due to complex homeostatic factors controlling translation and post- translational modification.

Thus, the predictability of protein translation and its possible utility as a diagnostic or therapeutic target are not necessarily contingent on the levels of gene expression due to the multitude of homeostatic factors affecting transcription and translation. Therefore, absent evidence of SEQ ID NO:310 protein expression, including the correlation to a specific diseased state, one of skill in the art would not be able to predictably use antibodies that bind the protein or polypeptide of SEQ ID NO:310 as a diagnostic or therapeutic tool. The specification does not predict or show whether the protein or polypeptide of SEQ ID NO:310 would be overexpressed or under expressed in a specific, diseased tissue compared to the healthy tissue control, for

example. In the absence of a direct correlation between the up-regulation of transcription and translation of the protein of SEQ ID NO:310 associated with a specific disease state, one of ordinary skill in the art would be unable to use antibodies specific for the protein of SEQ ID NO:310 for immunotherapy.

Even if the protein of SEQ ID NO:310 were expressed in fetal liver and fetal spleen, the mere presence of the protein provides no guidance as to its function, nor does the suggestion that it is "involved in lymphopoiesis" or "may play a role in the regulation of cellular division" indicate how the protein is involved or what role the protein plays in these biological processes or, how the protein or an antibody to the protein could be used.

In view of the lack of predictability of the art to which the invention pertains as evidenced by Fu et al., Powell et al., Vallejo et al., Lewin B. and Jang et al and lack of guidance in the specification related to using antibodies that specifically react with protein of SEQ ID NO:310 for immunotherapy, undue experimentation would be required to practice the claimed antibodies in a diagnostic or therapeutic setting with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed invention and absent working examples providing evidence which is reasonably predictive that the claimed antibodies are effective for immunotherapy.

b. Claims 7, 29, 44 and 67 also broadly encompass antibodies that bind to the glycosylated protein having the sequence of amino acid residues 25-136 of SEQ ID

NO:310 (protein consisting of the mature form of the polypeptide encoded by the HEMAE80 cDNA contained in ATCC Deposit Number 97975.

The specification teaches antibodies that bind to the polypeptide or polypeptide fragments of SEQ ID NO:310 , wherein the antibodies bind antigenic epitopes of SEQ ID NO:310 that contain a sequence of at least seven amino acids, more preferably at least nine amino acids and most preferably between about fifteen to about thirty amino acids (see page 373, lines 24-37).

The specification does not teach antibodies that bind carbohydrate moieties and does not provide any working examples to assist one skilled in the art to make antibodies that bind carbohydrate moieties.

Recognition of carbohydrate moieties bound by antibodies is a complex and unpredictable task. Unlike linear amino acid epitopes, which can be readily synthesized in vitro and against which other antibodies can be readily made, carbohydrate epitopes are more complex and difficult to synthesize. Knight (BioTechnology Vol 7 No 1, Jan 1989) likens this task to wrestling with a cloud. She states that prediction and control of the expression of oligosaccharide remains elusive and threatens to remain so from some time and the challenge is a daunting one. Knight goes on to explain that the structure of carbohydrates is much more complex than that of proteins. Dwek likens the task of sequencing a carbohydrate to simultaneously sequencing 40 or 50 proteins. Because carbohydrate structures are a branching series of linked rings, they can combine in many more ways that can linear peptide chains. For comparison, consider that while three amino acids can combine in only six ways, three carbohydrate

monomers can form over 1,000 different trisaccharide structures (see page 39, first column, third and fourth full paragraphs). One skilled in the art would reasonably conclude that, even if one had known that the antigenic epitope comprised carbohydrate moieties, the synthesis of potential carbohydrate moieties would require undue experimentation.

Even if one skilled in the art were able to identify a region of a glycosylated protein that bound a particular antibody, Knight teaches the unpredictability of knowing the exact structure found in that glycoprotein. Knight states that on top of this amazing diversity, nature adds what glycobiologists call micro heterogeneity in the form of discrete subsets -glycoforms- of a glycoprotein. These may have difference physical and biochemical properties. One skilled in the art would reasonably conclude that these different physical and biochemical properties encompass expression of different epitopes. Knight summarizes that the demographics of its glycoform population determine the composite activity of a glycosylated compound. According to Rademacher, Parekh and Dwek, any given glycoprotein that consists of different glycoforms will have a composite activity, reflecting a weighted average of the activity and incidence of each glycoform (page 39, third column, second full paragraph).

In summary, antibodies bind to structural shapes that may be linear stretches of amino acids, conformational determinants formed by the folding of peptides, carbohydrate moieties, phosphate or lipid residues or a combination thereof. The nature of the antigenic epitope was unknown at the time of filing. While multiple antibodies can be readily made to linear peptide sequences, the same is not true of

antibodies that recognize non-linear conformational determinants such as carbohydrate epitopes. Therefore, in weighing the factors to be considered in determining whether or not the practice of a claimed invention would require undue experimentation, as set forth in In re Wands (8 USPQ 2d at 1404), the weight of the analysis clearly favors a finding of undue experimentation.

11. Claims 38-75 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description.

It is unclear if a cell line, which produces a cDNA having the exact chemical identity of the HEMAE80 cDNA is known and publicly available, or can be reproducibly isolated without undue experimentation. Therefore, a suitable deposit for patent purposes is required. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed.

Because one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the claimed HEMAE80 cDNA, a suitable deposit is required for patent purposes, evidence of public availability of the claimed HEMAE80 cDNA or evidence of the reproducibility without undue experimentation of the claimed antibody, is required.

Applicant's acknowledgement of the deposit of the HEMAE80 cDNA as ATCC deposit number 97975 on pages 327 and 391-392 of the specification are an insufficient assurance that the required deposit has been made and all the conditions of 37 CFR 1.801-1.809 met.

If the deposit is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit of the HEMAE80 cDNA has been accepted by an International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent on this application. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

If the deposit of the HEMAE80 cDNA is not made under the provisions of the Budapest Treaty, then in order to certify that the deposit complies with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If a deposit is made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at (571) 272-0827 from 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.

Official papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The official fax number for Group 1600 where this application or proceeding is assigned is (703) 872-9306.

Respectfully,
David J. Blanchard
571-272-0827

LARRY R. HELMS, PH.D
PRIMARY EXAMINER